

**REMARKS**

Applicants have amended their claims in order to further clarify the definition of various aspects of the present invention. Specifically, the subject matter of claim 5 has been incorporated into claim 1; moreover, in view thereof, claims 5, 6, 13 and 14 have been cancelled without prejudice or disclaimer.

In addition, Applicants are adding new claims 31 and 32 to the application. Claims 31 and 32, dependent respectively on claims 1 and 31, respectively recites that the thickening agent is the layer-structure clay material; and that the method includes application of a tooth bleaching composition including the layer-structure clay material as the thickening agent.

Initially, it is respectfully requested that the present amendments be entered. Noting, in particular, incorporation of the subject matter of claim 5 into claim 1, the sole independent claim in the application, it is respectfully submitted that the present amendments materially limit issues remaining in connection with the above-identified application; and, at the very least, present the claims in better form for appeal. Since the claim amendments incorporate the subject matter of a previously considered claim into claim 1, and (in claim 31) further define the thickening agent as one of the listed thickening agents in claim 1, it is respectfully submitted that the present amendments clearly do not raise any new issues, including any issue of new matter. Noting the additional bases for rejection in the Office Action mailed July 23, 2003, as well as clarification of remarks by the Examiner therein, it is respectfully submitted that the present amendments are clearly timely.

In view of all of the foregoing, it is respectfully submitted that Applicants have made the necessary showing under 37 CFR § 1.116(c); and that, accordingly, entry of the present amendments is clearly proper.

The rejection of claims 1-8, 11-16, 19, 21-23, 25 and 26 under 35 USC §102 as anticipated by, or, in the alternative, under 35 USC §103(a) as obvious over, U.S. Patent No. 5,902,568 to Ryles, et al., is noted. It is respectfully submitted that Ryles, et al. discloses a method for whitening teeth which includes use of first and second compositions, forming an oral composition, each of the first and second compositions being stored separately from one another prior to time of use, the first composition containing from 0.01-20% of a peroxide by weight of the oral composition, and the second composition containing from 0.05 to 60% of a bicarbonate salt by weight of the oral composition, the oral composition having a pH from 9.0 to 12. See from column 1, line 63 to column 2, line 12. Note also column 2, lines 31-35. This patent describes that the peroxide-containing composition may either be a liquid, paste or gel, preferably the latter; and that when the peroxide composition is intended as a gel, it is usual to employ with water a thickening agent that is a cross-linked acrylic polymer. See column 3, lines 16-20 and 34-37. This patent goes on to disclose that the bicarbonate-containing composition of the oral composition is preferably an opaque paste (see column 3, lines 61-63), and that a natural or synthetic thickening agent may be present in an amount from 0.1 to 10%, preferably 0.5-5% by weight, of the second composition. See column 4, lines 18-24. Note particularly lines 20-24 of column 4, disclosing specific thickeners. Note further column 4, line 61 to column 5, line 1 of Ryles, et al.

It is noted that Ryles, et al. does not disclose, and it is respectfully submitted that this reference would not have suggested, the specific thickening agents set forth in claim 1, much less wherein the thickening agent is the layer-structure clay material as in claim 31; or the viscosity in the present claims. It is respectfully submitted that the layer-structure clay material is particularly preferred, because the clay takes water molecules into a unit space between layers and swells; by utilizing this property, the hydrogen peroxide in the bleaching agent can easily and very effectively be held adhered onto the surface of the teeth. See page 11, lines 5-14 of Applicants' specification.

In addition, by use of the layer-structure clay minerals, there is no need to use a high speed mixer for providing the composition including the thickening agent.

Furthermore, by use of the layer-structure clay material, phosphoric acid or phosphate as the thickening agent, active oxygen generated by photocatalyst action of titanium dioxide is not only used for the tooth bleaching but is also consumed for the reaction with the thickening agents, so that it is preferred to use the layer-structure clay mineral, phosphoric acid or phosphate.

In the paragraph bridging pages 3 and 4 of the Office Action mailed July 23, 2003, the Examiner lists various natural or synthetic thickening agents disclosed in Ryles, et al. The Examiner goes on to conclude, without any evidence in support thereof, that other known natural or synthetic thickening agents would be "immediately envisioned" obvious to select species. However, particularly in view of the advantages achieved by the present invention, using the specific thickening agents as in the present claims, it is respectfully submitted that compositions

including the specifically recited thickening agents would have neither been disclosed nor suggested by Ryles, et al.

Moreover, Applicants respectfully traverse the conclusion by the Examiner, without evidence or reasoning in support thereof, that Ryles, et al. discloses compositions with a viscosity within the range set forth in claim 1. Without such evidence or reasoning, clearly the prior art rejection is improper.

In addition, it is respectfully submitted that various thickening agents (e.g., silica gel) do not achieve advantageous results of increased viscosity as achieved by the present invention. In this regard, attention is respectfully directed to the enclosed (unsigned) Declaration under 37 CFR § 1.132 of H. Kurata, showing viscosities of various compositions including compositions containing silica gel. It is respectfully submitted that this Declaration shows that not all thickening agents would have achieved the advantages according to the present invention, including viscosity of the composition. For this reason also, Ryles, et al. would have neither taught nor would have suggested the presently claimed invention, including viscosity of the composition.

Entry and full consideration of the enclosed Declaration is respectfully requested, notwithstanding finality of the Office Action mailed July 23, 2003, as this Declaration addresses issues newly raised by the Examiner in this Office Action mailed July 23, 2003, and is thus timely.

Applicants respectfully traverse the obviousness-type double patenting rejection over the claimed subject matter of U.S. Patent No. 6,231,343 to Ishibashi, et al.; and the provisional obviousness-type double patenting rejection over United States Patent Application No. 10/109,868 (as evidenced by United States

Patent Application Publication No. US 2002/0177097, to Eguchi, et al). To clarify the record, it is respectfully submitted that the Eguchi, et al., published application is No. 2002/0177,097, not 2002/0177,091 as identified by the Examiner. It is respectfully submitted that neither of Ishibashi, et al. or Eguchi, et al. claim a composition or method including, inter alia, the thickening agent, or advantages achieved by such composition including such thickening agent; and, accordingly, the obviousness-type double patenting rejections, either provisional or actual, are improper.

In the paragraph bridging pages 4 and 5 of the Office Action mailed July 23, 2003, the Examiner alleges that the undersigned "refused" to furnish the Examiner with copies of Application No. 10/109,868 (Eguchi, et al.). As clearly apparent from the published application of Eguchi, et al., and as would have been clear to the Examiner if he had reviewed the file of the application published as Eguchi, et al., the undersigned is not counsel of record for Eguchi, et al. The undersigned did not refuse to furnish copies, but was unable to do so based upon the time for prosecuting the above-identified application.

In any event, it is respectfully submitted that the claimed subject matter of Eguchi, et al., as well as the subject matter claimed in Ishibashi, et al., would have neither disclosed nor would have suggested a composition or method as in the present claims, including wherein the composition used comprises a thickening agent, much less the thickening agent as in the present claims, or the recited viscosity as in the present claims.

The rejection of the method claims in the above-identified application, under the judicially created doctrine of obviousness-type double patenting, set forth on

pages 8 and 9 of the Office Action mailed July 23, 2003, is respectfully traversed. As indicated previously, it is respectfully submitted that the claimed subject matter in each of U.S. Patent No. 6,231,343 and in Application No. 10/109,868 would have neither disclosed nor would have suggested such method of using the presently claimed composition, wherein such composition contains the specific thickening agent, and has the recited viscosity, and advantages thereof as described in Applicants' original disclosure.

It is respectfully submitted that the additional teachings of the references referred to on pages 8 and 9 of the Office Action mailed July 23, 2003, would not have rectified the deficiencies of the claimed subject matter in Application No. 10/109,868 and U.S. Patent No. 6,231,343, such that an obviousness-type double patenting rejection would be proper.

U.S. Patent No. 6,420,437 to Mori, et al. discloses a titanium oxide colloidal sol and process for preparation thereof, the sol being useable as a semiconductor photocatalyst and for various functional coating agents for the purpose of ultraviolet ray-absorption, stain prevention, hydrophilization, preventing fogging, preventing fungus, deodorizing and water treatment, the colloidal sol including specified amounts of titanium dioxide charged with negative electricity, together with a complexing agent and an alkaline substance. See, for example, column 1, lines 9-17, and column 2, lines 32-36.

Initially, it is respectfully submitted that the teachings of Mori, et al. would not have been properly applicable to a method for bleaching a discolored tooth as in Eguchi, et al. or Ishibashi, et al.; and, even assuming, arguendo, that the teachings of these references were properly combinable, such teachings would have neither

disclosed nor would have suggested the presently claimed method, including use of the composition containing the specific thickening agent, and the viscosity range of the composition as in the present claims.

U.S. Patent No. 6,319,513 to Dobrozsi discloses oral liquid pharmaceutical mucoadhesive compositions, which are aqueous and mucoretentive, the compositions being described most generally at column 2, lines 33-55 and including specified colloidal particles and a safe and effective amount of a pharmaceutical active. See also column 7, lines 62-67, disclosing that the compositions include a safe and effective amount of a particulate component, which includes colloidal particles selected from the group consisting of silica, titanium dioxide, clay and mixtures thereof.

Even assuming, arguendo, that the teachings of Dobrozsi were properly combinable with the subject matter claimed in either of Eguchi, et al. or Ishibashi, et al., such combined teachings would have neither disclosed nor would have suggested the presently claimed tooth bleaching composition having the recited amount of titanium dioxide and recited amount of thickening agent, with the recited viscosity of the composition, and particularly wherein the thickening agent is one of the agents as in present claim 1.

U.S. Patent No. 5,041,282 to Smigel (Smigel (III)) discloses a toothpaste consisting essentially of components, in amounts, as set forth from column 1, line 58 to column 2, line 25. This patent discloses that the toothpaste includes a thickening agent in an amount of 1.0-15% by weight, and that the thickening agent can be corn starch. See column 2, lines 34 and 35.

U.S. Patent No. 5,597,554 to Wagner (Wagner (II)) discloses a system employing a mixture of conventional toothpaste in combination with a dentifrice preparation having a peroxide compound as an active constituent, the conventional toothpaste having from approximately 20% to 50% abrasive constituent comprising metal salt. See column 1, lines 48-53. This patent discloses that the dentifrice can include, inter alia, a thickener. See column 2, lines 41-59.

Even assuming, arguendo, that No. 5,041,280 or No. 5,597,554 were properly combinable with the subject matter claimed in Ishibashi, et al. or Eguchi, et al., such combined subject matter would have neither disclosed nor would have suggested the presently claimed method, including use of the composition having one of the specified thickeners, particularly with an amount of the thickener and titanium dioxide as in the present claims, and viscosity of the composition, providing the advantage of a composition which can easily be provided and yet which can easily and effectively adhere to a tooth surface during the bleaching.

U.S. Patent No. 5,759,251 to Nakamura, et al. discloses a titanium dioxide ceramic paint suitable for coating glass, metal, ceramic and plastic materials, the paint including at least one member selected from the group consisting of orthotitanic acid, titanium (IV) ions and peroxotitanic acid, and crystalline titanium dioxide colloidal particles having an average particle size of 0.001 to 0.2  $\mu\text{m}$ , the weight ratio of the components being defined, with the paint being substantially free from impurity ions. See column 2, lines 46-59.

Initially, it is respectfully submitted that one of ordinary skill in the art concerned with in Eguchi, et al. and Ishibashi, et al., directed to teeth bleaching systems, would not have looked to a ceramic paint as in Nakamura, et al.



In any event, even assuming, arguendo, that the subject matter claimed in Ishibashi, et al., or Eguchi, et al. would have been properly combinable with the teachings of Nakamura, et al., such combined teachings would have neither disclosed nor would have suggested the presently claimed subject matter, including the specific thickening agent, and amounts thereof and amounts of the titanium dioxide, and viscosity of the composition, and advantages thereof as discussed in the foregoing.

It is respectfully submitted that each of Ishibashi, et al. (B/N on PTO-892), Dobrozsi, Wagner (I-II) and Smigel (I, II and III) (each from the PTO-892) would have neither disclosed nor would have suggested the presently claimed subject matter, including the thickening agent as in claim 1, particularly the thickening agent as in claim 31, and amount of the thickening agent together with amount of the titanium oxide, and with the composition having the viscosity as in the present claims.

Ishibashi, et al. discloses a method for bleaching a discolored tooth, including the steps of applying a solution/paste of a titanium dioxide powder and hydrogen peroxide solution onto the surface of the discolored tooth, and irradiating this area with light to bleach the tooth based on the resultant photocatalytic action. See column 4, lines 28-32. Note also column 5, lines 8-21, describing the bleaching agent; and column 5, lines 53-59, describing that a fabric, paper, glass cloth, ceramic paper, an organic gel, an inorganic gel, or the like can be impregnated with the bleaching agent.

It is respectfully submitted that this reference does not disclose, nor would have suggested, a composition as in the present claims, including the specific

thickening agent as in the present claims, much less the amount thereof, and/or viscosity of the composition.

The contention by the Examiner that the description of organic gel and inorganic gel, in column 5, lines 53-59, of Ishibashi, et al., constitute "thickening agents", is respectfully traversed in connection with the method disclosed in Ishibashi, et al, thus, it is emphasized that according to Ishibashi, et al. the bleaching agent is impregnated in the organic gel or inorganic gel, or fabric, paper, glass cloth or ceramic paper. Thus, it is respectfully submitted that according to Ishibashi, et al., the organic gel or inorganic gel acts as a material impregnated with the bleaching agent, and it is respectfully submitted that this disclosure would have neither taught nor would have suggested the present invention, including the thickening agent, much less the specific thickening agent and amount thereof or viscosity of the composition.

In particular, it is respectfully submitted that the amount of the organic gel and of the inorganic gel in Ishibashi, et al., wherein the bleaching agent is impregnated in the gel, would be much larger than the amount of the thickening agent as recited in the present claims; and that Ishibashi, et al. would have neither taught nor would have suggested the presently claimed invention, including relatively small amount of thickening agent as in the present claims.

Dobrozsi, Wagner (II), and Smigel (III) have been previously discussed.

U.S. Patent No. 5,302,374 to Wagner (Wagner (II)) discloses an oral hygiene system whereby a quantity of dentifrice comprising a blend of relatively abrasive free constituents including a corn starch base and hydrogen peroxide as an active ingredient is placed upon the bristles of a toothbrush along with a quantity of

conventional toothpaste having from approximately 20% to 50% abrasive constituent comprising a metal salt. See column 1, lines 44-51. This patent further discloses in column 2, lines 47-64, that the system can also include a thickener.

U.S. Patent No. 4,690,776 and No. 4,603,045 (respectively (Smigel (II) and (Smigel (I)) disclose a toothpaste composition consisting essentially of various components, including corn starch and cellulose gum as thickening agents, together with titanium dioxide, the components being included in specific amounts. See column 1, line 48 to column 2, line 9, together with column 2, lines 24, 25 and 42, of No. 4,603,045, as well as the paragraph bridging columns 1 and 2, with column 2, lines 33, 34 and 51, of No. 4,690,776.

It is respectfully submitted that the teachings of Dobrozsi, Wagner (I and II) and Smigel (I, II, and III) would have neither disclosed nor would have suggested the presently claimed subject matter, including the recited thickening agent and amount thereof, particularly together with the amount of titanium dioxide, and viscosity of the bleaching composition, as in the various claims, noting particularly claims 1 and 31, and advantages thereof.

Japanese Patent Document No. 11-92351 (Ishibashi), as described in the English Abstract thereof, discloses attaching a solution/paste of powder of titanium dioxide and hydrogen peroxide onto the surface of a discolored tooth and irradiating the attached part with light to bleach the tooth based on a photocatalytic action caused by the light.

It is respectfully submitted that this reference does not disclose, nor would have suggested, incorporation of a thickener as in the present claims, much less the

specific thickener recited therein, and amount thereof, as in the present claims, and advantages thereof as discussed previously.

It is respectfully submitted that the additional teachings of U.S. Patent No. 5,032,178 to Cornell, Japanese Patent Document No. 60-75413 and Japanese Patent Document No. 51-59097 would not have rectified the deficiencies of No. 11-92351, such that the presently claimed invention as a whole would have been obvious to one of ordinary skill in the art.

Cornell discloses a dental composition and method for bleaching vital and non-vital teeth, the composition preferably being packaged as a two-component system, including a nonaqueous component adapted to be mixed with a concentrated aqueous solution of hydrogen peroxide to form an aqueous paste or gel for direct in-situ application to the teeth to be bleached, with the first component including in combination an inert silica gelling agent; a catalytic accelerator; an agent for providing thixoplasticity and thickening properties to the composition, such as cellulose ethers and methyl vinyl ethers, and means for indicating completion of the bleaching treatment of the teeth, including a redox color indicator for transforming from one color to another in response to the dissociation of hydrogen peroxide over a given period of time. See column 2, lines 40-55.

Japanese Patent Document No. 60-75413, as indicated in the English Abstract thereof, describes a dentifrice composition including specific amounts of a binder including a montmorillonite, an abrasive and, if necessary, a surface active agent, the viscosity of the composition being adjusted to less than or equal to 600 poise.

Japanese Patent Document No. 51-59097, as seen from the English Abstract thereof, describes a gelled composition based on hectorite clay for a toothpaste, in which the clay is homogeneously mixed with a synthetic compound containing fluorine, tetrasodium, pyrophosphate as a deflocculating agent, sodium lauryl sulfate as a foaming agent, glycerin as a moisture-retaining agent and water.

Noting that Japanese Patent Document No. 11-92351 is directed to a bleaching technique wherein a solution/paste of specified components is attached on the surface of the discolored tooth, it is respectfully submitted that one of ordinary skill in the art concerned therewith would not have looked to the teachings of No. 51-59097 or of No. 60-75413, directed to dentifrice compositions (e.g., which are to be removed speedily from the teeth).

In any event, even assuming, arguendo, that the teachings of the applied references were properly combinable, such teachings would have neither disclosed nor would have suggested the presently claimed invention, including the specific thickening agent used and amount thereof, as in claim 1 and particularly as in claim 31, and/or the viscosity of the composition, providing advantages as discussed in the foregoing. In this regard, No. 60-75413 discloses a composition having a viscosity much less than that of the composition of the present claims.

The reliance by the Examiner on U.S. Patent No. 5,032,178 as describing, as a thickening agent, a silica filling agent, on page 11, lines 8-13 of the Office Action mailed July 23, 2003, is noted. Again, attention is directed to the enclosed (unsigned) Declaration Under 37 CFR § 1.132 of H. Kurata, showing various viscosities and, in particular, the unexpectedly and disadvantageously low viscosity of the composition when utilizing silica gel as a thickening agent. Particularly in view

thereof, it is respectfully submitted that the combined teachings of the applied prior art, including Cornell, would have neither disclosed nor would have suggested the present invention, including the specific thickening agents and advantages thereof.

In view of the foregoing comments and amendments, entry of the present amendments, and reconsideration and allowance of all claims presently in the application, are respectfully requested.

To the extent necessary, Applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to the Antonelli, Terry, Stout & Kraus, LLP Deposit Account No. 01-2135 (Docket No. 396.40960X00), and please credit any excess fees to such Deposit Account.

Respectfully submitted,

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